DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

30 NOV 2016

MEMORANDUM FOR SGVU
ATTN: DR JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your email bulletin, entitled **59th Medical Wing IRB FAQs** published in **59 MDW Clinical Research Division Knowledge Exchange** in accordance with MDWI 41-108, has been approved and assigned local file #**17000.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Calcote, Joshua - Contractor, 59 MDW/SGVU	☐ YES ☒ NO	N/A

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

N/A

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

59th Medical Wing IRB FAQs

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☒ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)
For posting onto the 59 MDW Clinical Research Division Knowledge Exchange website and within the 59 MDW email bulletin

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
N/A	

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Calcote, Joshua C. - joshua.calcote.ctr@us.af.mil	210-292-7143

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Dr. Joshua C. Calcote	Contractor	59 MDW/SGVU	
b.			
c.			
d.			
e.			

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
Joshua C. Calcote, Contractor		November 28, 2016
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**22. APPROVING AUTHORITY'S SIGNATURE**	**23. DATE**
Dr. Earl Grant, Jr., GS-14, DAF	GRANT.EARL.JR.1126544380	November 29, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 11/30/2016	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17000
26. DATE REVIEWED 30 Nov 2016		27. DATE FORWARDED TO 502 ISG/JAC

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The 59th Medical Wing IRB FAQs are approved for posting.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Rocky Calcote, PhD, Clinical Research Administrator	CALCOTE.ROCKY.D.1178245844	

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED November 30, 2016	40. DATE FORWARDED TO 59 MDW/SGVU November 30, 2016

41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613	November 30, 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

IRB FAQs

Where can I find 59 MDW Institutional and IRB policies for research involving human subjects?

You can access all 59 MDW IRB Operating Instructions HERE.
You can access all 59 MDW Institutional policies HERE.

My "mail.mil" emails are not sending correctly to the Office of Research Protocol Support. What is going on and how can I fix this?

We are currently experiencing issues with receiving mail.mil emails with attachments into our Office of Research Protocol Support organization box, but the Office of Research Protocol Support has developed a work-around where an investigator who wishes to contact us can directly send an email to individual Office of Research Protocol Support staff members or submit protocol documents to the AMRDEC Safe website (https://safe.amrdec.army.mil/safe/). We apologize for any inconvenience. We are currently working with IT Systems to get this issue resolved. Beginning 14 November 2016, all "us.af.mil" email accounts will be migrated into the "mail.mil" email account system, which should solve this issue. To ensure that we have received your submission during this process, please follow-up with a member of our Office of Research Protocol Support at (210)-292-2977, (210)-292-5819, or (210)-292-5203.

What is the Office of Research Protocol Support?

Reviewing research proposals to ensure human subjects are protected is a **BIG** job and an important one. The 59 MDW Office of Research Protocol Support, located in the Clinical Research Division building behind Wilford Hall, is the backbone of the IRB and assists the IRB with reviewing forms, templates, communication with researchers, and the generation of IRB Meeting Minutes, among many, many other duties. In FY16, the Office of Research Protocol Support maintained agreements with 58 institutions to serve as their IRB of Record and supported 219 human and human exempt studies. If you are in a residency program and require assistance with your scholarly activity and protocol preparation, this is the office you should visit first.

Do you have a question about your research protocol application, or do you want to obtain the forms to begin a research project?

Contact the Office of Research Protocol Support for help at: 59crd.protocol@us.af.mil or call them at 210-292-7141; DSN 554-7141.

When does the IRB meet?

IRB DATE	NEW PROTOCOL DEADLINE (4pm, 4th Monday of month prior to IRB)	PROGRESS REPORT/OTHER REPORT DEADLINE	
22 Nov 2016	**24 Oct 2016**	If study expires **23 Nov–26 Dec**, submit by:	**11 Oct 2016**
No Dec IRB		If study expires **27 Dec–24 Jan**, submit by:	**11 Oct 2016**
24 Jan 2017	**28 Nov 2016**	If study expires **25 Jan–28 Feb**, submit by:	**08 Nov 2016**
28 Feb 2017	**23 Jan 2017**	If study expires **29 Feb–28 Mar**, submit by:	**10 Jan 2017**
28 Mar 2017	**27 Feb 2017**	If study expires **29 Mar–25 Apr**, submit by:	**14 Feb 2017**
25 Apr 2017	**27 Mar 2017**	If study expires **26 Apr–23 May**, submit by:	**14 Mar 2017**
23 May 2017	**24 Apr 2017**	If study expires **24 May–27 Jun**, submit by:	**11 Apr 2017**
27 Jun 2017	**22 May 2017**	If study expires **28 Jun–25 Jul**, submit by:	**09 May 2017**
25 Jul 2017	**26 Jun 2017**	If study expires **26 Jul–22 Aug**, submit by:	**13 Jun 2017**
22 Aug 2017	**24 Jul 2017**	If study expires **23 Aug–26 Sep**, submit by:	**11 Jul 2017**
26 Sep 2017	**28 Aug 2017**	If study expires **27 Sep–24 Oct**, submit by:	**08 Aug 2017**
24 Oct 2017	**25 Sep 2017**	If study expires **25 Oct–28 Nov**, submit by:	**12 Sep 2017**
28 Nov 2017	**23 Oct 2017**	If study expires **29 Nov–26 Dec**, submit by:	**10 Oct 2017**
No Dec IRB		If study expires **27 Dec–22 Jan**, submit by:	**10 Oct 2017**

I have an idea for a project. Who should I talk to for help with preparing my protocol at the 59 MDW?
Contact the following individuals for assistance with human and exempt protocols:

Office of Research Protocol Support
292-2977/5819/4012
Ms. Rachel Montez – 292-4683
rachel.montez@us.af.mil

Statistics/Study Design/Funding
Dr. Anneke Bush – 292-7295
anneke.bush@us.af.mil

Research Education/Post-Approval Monitoring
Dr. Earl Grant – 292-5146
earl.grant.1@us.af.mil
Ms. Jennifer Palmer – 292-5819
jennifer.palmer.1.ctr@us.af.mil

Human Studies
Dr. Rocky Calcote – 292-5203
rocky.calcote.1@us.af.mil

Laboratory Services Branch
Dr. Thomas Gibbons – 292-7363
thomas.gibbons@us.af.mil

Pathology Support
LTC Michele Thompson – 292-6589
michelle.thompson.8@us.af.mil

I work at BAMC. Do you have information on the BAMC IRB submission process?
The Southern Regional Medical Command/Brooke Army Medical Center Institutional Review Board (SRMC/BAMC IRB), is overseen through the Regional Health Command Central Human Research Protections Office. BAMC has stopped accepting submissions through eIRB. Effectively 1 Nov 16, NEW submissions must be emailed to the SRMC/BAMC IRB at usarmy.jbsa.medcom-bamc.mbx.bamc-irb@mail.mil. This process will remain in place until further notice. All IRB submission instructions, forms, and templates are available at https://srmc-portal.amedd.army.mil/srmc_hq/clinops/Humanresearchprotectiveoffice/SitePages/Home.aspx. If you need assistance or additional information, please contact Ileana King-Letzkus at Ileana.e.king-letzkus.civ@mail.mil or Brenda Torres at brenda.c.torres2.civ@mail.mil.

What is the role of the Office of the Chief Scientist for development and dissemination of HRPP policies?
The Office of the Chief Scientist (59 MDW/ST) provides scientific review (to be presented to the IRB), merit review, assists with capability gaps, and supports GME and GHSE researchers. They also participate as a component of the HRPP in the HRPP Steering Committee (a guidance body which advises the AIO).

What do you do if a research subject has a complaint? Who do you report it to and when?
Complaints should be immediately reported via phone to the IRB via the Office of Research Protocol Support, followed by a formal report within 10 duty days and as part of your continuation review.

What is the difference between a data safety monitoring board (DSMB) and a data safety monitoring plan (DSMP)?
A Plan is required if the study is greater-than-minimal risk or if required by the IRB. A Board is indicated when the trial is intended to provide definitive information about effectiveness and/or safety of a medical or bio-behavioral intervention; there is a potential for the research to induce potentially unacceptable toxicity; evaluating a major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications; if it would ethically be important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed. A Board is generally expected to be utilized in the following situations:

- All Phase III studies, with the exception of low-risk behavioral and nutritional studies.
- Low-risk studies if the studies are exceptionally large, long term, and/or involve vulnerable subjects.
- Phase II clinical trials which are multicenter and randomized, with the exception of low-risk behavioral and nutritional studies.
- Phase II studies which are "high risk."
- Clinical trials of diseases with high mortality or morbidity, for clinical trials involving high risks, and for large, multicenter clinical trials.

- For some studies involving particularly vulnerable study participants or that utilize blinding.

What are some HRPP Responsibilities at the 59 MDW?
At the Organization level, the Institutional Official ensures all research participants are protected.
At the IRB and Ethics level, each research project is evaluated to ensure all research participants are protected.
At the Researcher and Staff level, they have the protection of the rights and welfare of research participants as a primary concern.

Who are the Institutional Official (IO) and Assistant Institutional Official (AIO) at 59 MDW?
The IO, MGen Iddins, is ultimately responsible for all human research activity at the 59 MDW.
The AIO, Dr. Deborah Niemeyer, has been designated by the IO to assist with the day to day operations of the HRPP however the IO maintains ultimate responsibility and accountability for the program.

What is the investigator responsibility for protecting human subjects at the 59 MDW?
The investigator is responsible and accountable for all activities they conduct that may be research, research involving human subjects, research involving human subjects that is exempt from prior IRB approval or research involving human subjects that requires prior IRB approval.

Who is responsible for protecting human research subjects at the 59 MDW?
Every member of the 59 MDW has a responsibility to protect research subjects. The 59 MDW Institutional Review Board (IRB), in conjunction with Principal Investigators, research staff, IRB Office staff, 59 MDW leadership, you and me, and even the Surgeon General of the Air Force, are some of the folks responsible for safeguarding research subjects. Learn more about IRBs here. All 59 MDW personnel and patients are encouraged to report any research-related concerns/comments or ask any questions regarding the treatment of human research subjects. If you see anything out of the ordinary that concerns you do not hesitate to call or email at 292-7141 or 59crd.protocol@us.af.mil.

Do you have a question about your research protocol application, or do you want to obtain the forms to begin a research project?
Contact the IRB Office of Research Protocol Support for help at: 59crd.protocol@us.af.mil or call them at 210-292-7141; DSN 554-7141.

So you have submitted a proposal to the IRB Office of Research Protocol Support, now what?
Depending on the kind of study you are conducting, the IRB Office of Research Protocol Support and/or Initial Reviewer will work with you to ensure your proposal is complete and considers all aspects of your research. Then, either a Designated Reviewer or the full, convened IRB will review your proposal, critique it, and provide to you a decision: Approved; Conditionally Approved; Tabled/Deferred (until the next meeting); or Disapproved. If approved, you may begin your research.

Do IRB records get internally audited by someone at the 59 MDW?
The Director of the Clinical Research Division's Office of Quality and Education regularly audits IRB records for compliance purposes. In addition, external agencies, such as the FDA and the Surgeon General's Research Oversight and Compliance Division, audit IRB records as well.

Why are audits not random and so time-consuming to prepare for?
All studies are subject to auditing. Dr. Grant is the Post-Approval Monitor for 59 MDW protocols and he can be contacted at 210-292-5146; earl.grant.1@us.af.mil. To educate PIs on the audit process and how to maintain protocol documentation, he and his staff will meet with PIs before they receive their IRB approval letter to ensure they understand the IRB Post-Approval Monitoring Process. There are no requirements to notify a PI of an audit and audits may be conducted unannounced. Prior notification of an audit is a courtesy we provide for the investigator, so that auditors can work within the PI's schedule. It should not take any time preparing for the audit as long as the study binder and folders are maintained appropriately and continuously updated as the research study progresses. The

research binder template describes the information that must be maintained and continuously updated throughout the life of the study.

Who are investigators?
The term "investigator" refers to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

Must investigators obtain IRB approval before involving human subjects in non-exempt research?
Investigators are responsible for obtaining IRB approval before beginning any nonexempt human subjects research (32 CFR 219.109(a) and (d)); investigators should follow institutional policies and procedures for IRB review.

Are investigators responsible for obtaining and documenting informed consent?
Investigators are responsible for obtaining and documenting the informed consent of research subjects or their legally authorized representatives, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent, respectively (32 CFR 219.116, 32 CFR 219.117). Investigators must give a copy of the informed consent document to each research subject (or the subject's legally authorized representative), and keep the signed original or a copy of it for their records (32 CFR 219.117(a); 32 CFR 219.115(b)).

Why is the Informed Consent Document template so long?
Informed consent is one of the primary ethical requirements of research with human subjects as it reflects the basic principle of respect for persons and is much more than just a signature on a form. The 59 MDW IRB will require documentation of informed consent or may waive documentation based on 32 CFR 219.116, with the exception as stated in 10 U.S.C. 980. The 59 MDW Human Research Protection Program (HRPP) goal is that each research subject is fully informed about study procedures, risks/benefits, confidentiality, alternatives, cost, etc. Informed Consent is an educational process that takes place between the principal investigator (PI) and the prospective subject and the PI uses this to confirm that their potential subjects understand what the research entails and has the opportunity to ask questions. The goal for the 59 MDW ICD template is to provide the PI the ability to detail all the information they need to educate the subject so that prospective subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The 59 MDW ICD template has been developed to cover most of the contingencies seen by the IRB when reviewing a non-exempt human research study. There are certain sections that are required by 32 CFR 219 and include regulatory language that cannot be altered, especially for active duty and DoD beneficiaries. The PI has the option to delete certain sections of the ICD if they do not pertain to their study. However, the 59 MDW Institutional Review Board (IRB) will make the final determination if a given section is required or not or should be modified. POC for this item is Dr. Rocky Calcote. His phone number and e-mail is (210) 292-5203; rocky.calcote.1@us.af.mil.

To advertise the 59 MDW informed consent document (ICD) process, the 59 MDW Clinical Research Division offers training to resident groups. For information on this training, please contact Dr. Earl Grant at (210) 292-5146; earl.grant.1@us.af.mil. These training sessions can be made available to any of the residency directors and will enable researchers to ask questions on the ICD.

What should investigators do if they want to revise an IRB-approved research study?
If investigators wish to modify an ongoing IRB-approved research study, they must submit a request to the IRB and receive IRB approval before implementing the proposed modification, unless the change is designed to eliminate an apparent immediate hazard to subjects (32 CFR 219.103(b)(4)).

What should investigators do when considering changes to an exempt study that could make it non-exempt?
Investigators should consult with the 59 MDW IRB Office of Research Protocol Support whenever questions arise about whether planned changes to an exempt study might make that study nonexempt human subjects research.

Who can make the exempt determination for a human research study?
The regulations specify who at an institution may determine that research is exempt under DoDI 3216.02_AFI 40-402, Enclosure 3, section 3.a.(1)(a). Please contact the 59 MDW IRB Office of Research Protocol Support at 59crd.protocol@us.af.mil or 292-7141 for questions related to determination.

Does my protocol qualify as non-human research?
Research projects may be classified as "not involving human subjects" if they involve obtaining, collecting and/or using non-identifiable or anonymous private information or human biologic specimens or if they do not collect information about an identified living individual. Research projects may be classified as not constituting research if the study isn't designed to develop generalizable knowledge.

What constitutes a conflict of interest?
A COI arises when there is a divergence between an individual's private interests, or the interests of the individual's immediate family, and his or her professional obligations related to the research.

What should investigators do if IRB approval expires?
If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study (32 CFR 219.103(b)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB (32 CFR 219.103(b)(5)).

I am a contractor not affiliated with the Department of Defense and I want to conduct a human research study with the 59 MDW utilizing active duty and DoD beneficiary patients as study subjects to investigate a new medical device. What steps must I take in order to secure the 59 MDW IRB as my IRB of Record?
In order for our 59 MDW Institutional Review Board (IRB) to become the IRB of Record for your study, several actions must occur first:

1. As a contract employee, your company must have their own Federal-wide Assurance (FWA) to conduct human research. Otherwise, you will be required to have a 59 MDW Individual Investigator Agreement (IIA) approved through our Authorized Institutional Official (AIO), Dr. Niemeyer. If your company has their own FWA, then we will also need an Institutional Agreement for IRB Review (IAIR) between your company and the 59 MDW. This agreement basically states that your company and its employees engaged on the research study in question will abide by the regulatory oversight by the 59 MDW IRB, plus all federal, DoD, Air Force, and state research regulations governing non-exempt human research. You must be covered by an FWA or an IIA before you become engaged on a DoD-supported or -conducted human research study. Your FWA number and expiration date or your IIA number and expiration date must be provided to the 59 MDW IRB when reviewing your study.

2. Has your medical device been FDA approved for clinical use? Do you have an FDA 510(k) premarket approval (PMA) that demonstrates the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to PMA? If your device is considered investigational and you do not have a 510(k) PMA, then you will need to get an FDA investigative device exemption (IDE) approval before it can be used on patients. A copy of the FDA 510(k) PMA or FDA IDE approval letter must be provided to the 59 MDW IRB when reviewing your study.

3. The study will require a 59 MDW Active Duty military member or DoD employee to be the Principal Investigator (PI) on the study. The 59 MDW IRB is not permitted to approve a civilian study without DoD investigators participating on the study. Therefore, a 59 MDW PI will have to be identified to be responsible for the study.

4. Your study would be considered an AF study with your company being the sponsor. In order for your company to be the sponsor for the study, your company will have to establish a Clinical Research and Development Agreement (CRADA) with the 59 MDW. Please contact the Office of the Chief Scientist at 210-292-2097 or

59mdw.st.hrpp@us.af.mil for additional guidance. If the company needs to train the DoD investigators on the use of your device, then this will be covered in the CRADA, as well. The CRADA will allow you to provide your device for use on a non-exempt research study involving human subjects and permit you to receive a copy of the research data that can be used to request full FDA approval of your device. If you happen to have a DUNS number and CAGE code in order to work with the federal government, these numbers do not apply when performing clinical research investigations with DoD beneficiary patients, e.g., Active Duty members, dependents and retirees. This is the reason that a CRADA must be established with the 59 MDW.

5. The 59 MDW PI will be responsible to work with your company to develop the human research study and complete all the necessary protocol documents for submittal to the 59 MDW IRB for final review/approval. All patients will have to be consented and must sign an Informed Consent Document (ICD) and HIPAA Authorization Document, in order to become participants on the research study. If your research study requires research-related medical interventions (i.e., blood draws for lab analysis), the PI will have to establish local support agreements in order to perform these interventions or other diagnostic procedures. For example, blood draws and lab analysis would require agreements with the local study site (i.e., Wilford Hall Ambulatory Surgical Center and/or Brooke Army Medical Center) to obtain the blood samples and then either the 59 MDW Clinical Research Division (CRD) research laboratory or the 59 MDW/ST Center for Advanced Molecular Detection (CAMD) research laboratory for performance of lab analysis. A laboratory cost for supply use may be charged for the lab analyses. The PI or another research assistant will be responsible to obtain data from each patient using your medical device for additional diagnostic data.

What is an Assurance?

An Assurance of Compliance is a formal written, binding agreement that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. The AF assurance is a signed agreement between the institutional official of an institution engaged in Air Force sponsored research and HQ AFMSA/SGE-C which assures that all research will be performed according to the requirements of AFI 40-402, 32 CFR 219 and 10 United States Code 980.

What do I need to know about Federal-wide and DoD Assurances when conducting research with the 59 MDW?

The Secretary of Defense has delegated the authority to approve DoD Assurances and DoD Addenda to each Service's Surgeon General. Each DoD institution engaged in non-exempt human research must have an approved ***DoD Assurance***, in which the institution ensures full compliance with 32 CFR 219; Title 10 United States Code 980 (10 USC 980); DoDD 3216.02; 45 CFR 46 (Subparts B, C, and D, as made applicable by DoDD 3216.02); Food and Drug Administration regulations and guidance (e.g., 21 CFR Parts 50, 56, 312, and 812) where applicable; and any other applicable federal, state and local laws. All active duty military and DoD employees of the institution are authorized to conduct research under this assurance. The DoD Assurance must be renewed every 3 years.

Contractors are not considered employees or agents of a federal agency and are not covered under the facility's DoD Assurance to conduct research. Contract employees and non-DoD personnel of non-DoD institutions (e.g., universities, pharmaceutical companies, laboratories, etc.) must have an existing ***Federal-wide Assurance (FWA)*** approved through the Department of Health and Human Services in order to engage in non-exempt human research in the civilian sector. The FWA does not acknowledge key DoD policies, directives and other regulatory requirements for human research and protection. The FWA will need to be renewed no later than every 3 years.

If a non-DoD person is a self-employed contractor or is an employee of a contractor or non-DoD agency not covered by an FWA or DoD Assurance, then the individual must obtain an ***Individual Investigator Agreement (IIA)*** endorsed by the DoD Institutional Official (IO)/Authorized Institutional Official (AIO), whose facility has been issued a DoD Assurance. Once the IIA is approved, the individual is now covered under the institution's DoD Assurance and the individual may now participate on any DoD sponsored or conducted research within that respective facility. Normally, the IIA is not protocol specific, but encompasses all research conducted within the institution. When an individual signs an IIA, he or she agrees to comply with the rules of the DoD institution, while the institution agrees to allow the individual to conduct

research under its authority. The IIA is non-transferable to any other DoD institution to conduct research. There is no expiration date normally for a signed IIA, unless the IO/AIO specifically states one.

DoD assurance requirements are driven by Title 32 Code of Federal Regulations Part 219 Para 103 (32 CFR 219.103) and DoD Directive DoDD 3216.02 (Para 4.3.3). Other specific Services' and Health Affairs assurance requirements are referenced in 32 CFR 219 and DoDD 3216.02. Research investigators need to be cognizant of mandated DoD assurance requirements for the protection of human subjects involved in DoD-supported or -conducted research. This mandate applies to all research with human subjects as the direct object of the research or as the indirect object of the research, to include the development and testing of military weapon systems, vehicles, aircraft and other material.

Federal assurances are accepted by all Services and DoD agencies and are used in facilitating joint research, as well as, collaborative research with non-DoD institutions, e.g., universities, laboratories, pharmaceutical companies, small businesses, etc.

All non-exempt human research must be reviewed and approved through an Institutional Review Board (IRB). For any DoD or non-DoD institution that lacks an internal IRB and is relying on another DoD Institutional Review Board (IRB) as their legal IRB of record, they must obtain a ***DoD Institutional Agreement for IRB Review (IAIR)***. The IAIR can be approved for a specific research study or for all future research efforts for the institution seeking reliance on another IRB's services. The IAIR is signed by the IO/AIO (for DoD organizations) or the CEO (for civilian organizations) of the engaged institution relying on the services of the IRB and the IO/AIO of the DoD institution supplying the IRB services. This agreement, when signed, becomes part of the engaged institution's DoD Assurance (for DoD organizations) or FWA (for civilian organizations). This document will negate the need to have multiple IRBs review/approve a multi-site study. With an IAIR in place, only one IRB of record is needed to have the legal oversight for a research study.

Due to the lengthy review/approval process to obtain an IIA for non-DoD employees or contract personnel, it is recommended that the Principal Investigator (PI) consider removing these individuals from their study temporarily, until it is approved through the IRB. Once approved, each individual can be added back to the study through a protocol amendment. If non-DoD employees and/or contract personnel remain on the study, the research proposal cannot be officially approved for implementation until each individual has evidence they are covered through an IIA. This could significantly prolong final protocol approval until this documentation is provided to the Office of Research Protocol Support.

If you have any questions concerning assurances for your study, please contact your local Office of Research Protocol Support. For those associated with the Brooke Army Medical Center, please contact Ms. Brenda Torres, Protocol Coordinator, at (210) 916-2598 or Ms. Ileana King-Letzkus, HIPAA Research Compliance, QA & Training Coordinator, at (210) 916-2000. For those associated with the 59th Medical Wing, please contact Dr. Rocky Calcote, Clinical Research Administrator, at (210) 292-5203.

What are the "steps" required to develop a research protocol, get it approved, implement the study, and publish study results?

1. Obtain "Good Clinical Practices" Training (FDA regulated studies for investigational drugs/devices)
2. Obtain "Collaborative Institutional Training Initiative (CITI)" Training for Human Research Protection
3. Develop a research idea
4. Conduct a scientific literature review
5. Draft a research protocol application and complete any required supporting documentation utilizing the appropriate templates found on the 59 Clinical Research Division (CRD) Knowledge Exchange website (CAC-accessible only).
6. Coordinate research protocol through your Department Heads for scientific review and approval and revise your protocol based on their review comments
7. Submit documentation for intramural or extramural funding support, as needed
8. Submit protocol to the 59 MDW Office of Research Protocol Support

- Revise protocol based on pre-review comments/corrections
- Provide all regulatory assurance documentation for investigators
- Provide all FDA approval letters for investigative drugs/devices (as applicable)

9. Present research protocol to the 59 MDW Institutional Review Board (IRB) for review
   - If Tabled: revise proposal and resubmit to the 59 MDW IRB based on substantive changes needed for the study
   - If Conditionally Approved as a Minimal Risk Study: revise protocol for expedited approval of all IRB- and Medical Legal-directed changes/corrections
   - If Conditionally Approved as a Greater-Than-Minimal Risk Study: revise proposal for expedited approval of all IRB- and Medical Legal-directed changes/corrections and submit to AFMSA/SGE-C for a final compliance review/approval through the AF/SG's Human & Animal Research Panel (SGHARP)
   - If Approved: can commence research study upon receiving 59 MDW Institutional Approval from the Authorized Institutional Official (AIO)
10. Order equipment/supplies through Contracting or the CRD, as needed, for the research study
11. Recruit research subjects for the study
12. Conduct the research
    - Provide "Progress Reports" and "Annual Continuing Review Reports"
    - Provide quarterly "FDA Progress Reports" if the study is FDA-regulated
    - Provide any reports for "Adverse Events" that may occur during the study
    - Provide any reports for "Unanticipated Problems Involving Risk to Subjects and Others (UPIRSO)" severe adverse events that have harmed research subjects during the study
13. Gather all research data and conduct data analysis
14. Submit a 59 MDW Form 3039 request for publication and presentation review to the 59 MDW CRD
15. Report all research findings through scientific peer-reviewed journals and through the Defense Technical Information Center (DTIC) database repository
16. Provide briefings, poster sessions, etc. to scientific meetings highlighting research outcomes

Are Principal Investigators required to attend the IRB meeting where their research proposal is being discussed?
PI attendance at an IRB Meeting has always been an option for the PI. It is NOT a requirement. However, it is highly recommended that the PI attend the IRB meeting or call into the meeting to discuss their research with the IRB members. If the PI does not attend the meeting and there are issues that cannot be resolved by the IRB, then the investigator's study will be tabled until the next IRB meeting. This is time lost for the PI, which could have been avoided. Again, this is an option for the PI. It is not a requirement. It is up to the IRB if a study requires review by a convened board or not. POC for the IRB is Lt Col Della Howell (della.howell@us.af.mil) or Dr. Rocky Calcote at 210-292-5203; rocky.calcote.1@us.af.mil.

Why did I receive grammatical and spelling corrections on my research proposal? Isn't the IRB supposed to focus on Human Subjects Protection?
The primary role of the 59 MDW IRB is to determine that human subjects on a research study are being protected. The 59 MDW IRB has appropriate expertise to evaluate the research. The IRB consists of scientific and non-scientific members, as well as, community representatives with a diversity of race, gender, and cultural backgrounds. The IRB may approve, disapprove, or require modification to proposed research. The operating instruction of the 59 MDW IRB, *HRPP OI-001*, can be found HERE. The 59 MDW IO or AIO may disapprove an IRB approved study, but may not reverse IRB disapproval. Human subject protection is determined by the protocol design, data collection methods, types of intervention, ICD, HIPAA Authorization, risks/benefits, confidentiality, vulnerable populations involved, etc. It is not a single criteria that is reviewed. Many facets of a study come into play.

To support the 59 MDW research mission, the 59 MDW IRB members and support staff conduct pre-review of protocols. This pre-review is not part of the IRB review and it includes grammar corrections as track changes to assist PIs to prepare documents that are ready to meet the IRB. Dr. Rocky Calcote (210-292-5203; rocky.calcote.1@us.af.mil) is the POC for pre-reviews and IRB reviews. Pre-review is a service to the PI as their research documents are not just reviewed by the

IRB for human subjects protection, but are also reviewed by AFMSA/SGE-C and, as needed, by the FDA and research sponsors. It is the responsibility of the PI to ensure their protocol is grammatically correct, understandable, and regulatory compliant (e.g., overuse of acronyms with no explanation, contradictive statements throughout the protocol, minimal information provided for clarity, mismatch of protocol design procedures and ICD procedures, not addressing appropriate regulatory protections for vulnerable populations, etc.). This is the reason for the Designated Reviewer pre-review process for each new study. We try to resolve most of these issues prior to the study being forwarded to the IRB for final review. The pre-review process is a service for the investigator. It is not mandated. Without a pre-review of a study, it would be forced to a convened IRB for review. In most cases, the IRB would identify the same needed corrections or changes to a study that may have been identified in the pre-review process, plus additional concerns based on a convened IRB review process. If the IRB determines there are too many changes/corrections needed for a study or the study is unclear, they could table the study until the next convened IRB meeting. This is time lost for the PI, which could have been avoided. Current support information is part of the research binder template on the KX website.

Can the IRB assist me with data collection for my study?

Gathering data for a research study is outside the scope of an IRB's duties. The investigator and their research team are responsible for all data collection and analyses. The 59 MDW/ST has resources available to assist PIs in preparing their documents for IRB review and in data collection. The POC for protocol documents is Ms. Rachel Montez at 210-292-4683; rachel.montez@us.af.mil.

What is research and when does an institution become engaged in research?

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [32 CFR 219.102(d)]. A *"human research subject"* is a living individual about whom an investigator conducting research obtains data through intervention or interaction or obtains identifiable private information [32 CFR 219.102(f)]. Private information or specimens are considered *"individually identifiable"* when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems [32 CFR 219.102(f)].

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. See 32 CFR 219.102(d), (f). Also, see OHRP definition of Engagement in Research.

In general, an institution is *"engaged"* in research whenever:

- The institution's employees or agents intervene (e.g., administer study-related investigative medications or investigational devices) or interact with human subjects for the purposes of non-exempt federally-conducted or -supported human research; or
- The institution's employees or agents obtain individually identifiable private information about human subjects for purposes of non-exempt federally-conducted or –supported human research, e.g., enroll subjects or obtain informed consent; or
- The institution receives a direct federal award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

Institutions are NOT engaged in research when their employees or agents:

- Act as consultants or analysts on research, but at no time obtain, receive, or possess identifiable private information.
- Perform commercial/clinical services (e.g., medical history, blood test, CT scan) or fee-for-service normally performed by the institution for non-research purposes and the services do not merit professional recognition or publication privileges.
- Receive de-identified/coded information or specimens for research, operating in accordance with an approved Assurance, and are unable to readily ascertain the identity of the subject(s) to whom the coded information or specimens pertain.

What is the research education policy for principal investigators, associate investigators, research coordinators, assistants and research monitors?

1. The 59 MDW IRB has determined that the only course that will fulfill initial investigator human research protection training requirements is the University of Miami CITI on-line course.
   - For Human Studies complete the Group 1 Module & 59 MDW-specific Module.
   - For Exempt Studies complete the Group 2 Module and 59 MDW-specific Module.
   - For Social/Humanistic/Behavioral research with humans complete the Group 3 Module and 59 MDW-specific Module.
   - For Exempt Social/Humanistic/Behavioral research with humans complete the Group 4 Module and 59 MDW-specific Module.

   Overall passing score is 80%. You must also pass each module with a score of 80% or better.

   This training is valid for 3 years from the initial training date and must be re-accomplished prior to the 3-year expiration date by completing the respective CITI Refresher Course. If an investigator's CITI training expires, they must be removed from the research study until the training is re-accomplished. If the Principal Investigator's CITI training expires, the 59 MDW IRB may make a determination to suspend the research until the PI re-accomplishes the training. The 59 MDW IRB may not approve a Continuing Review Report or amendment to a study, if the PI's training is not current. If a request is made to change the PI, the 59 MDW IRB may not approve the change, if the new PI does not have current CITI training.

2. New Human Studies – all new Human studies submitted to the 59 MDW IRB must document CITI training for the following research staff:
   - Principal Investigator (PI) – CITI certification must be received prior to IRB review.
   - Documentation of all others engaged in research must be received before final approval is granted, to include: Associate Investigators (AI), Research Coordinators, Research Monitors, contractor employees and non-DoD civilians. Being engaged in research means interaction or intervention with a living person for research purposes or obtaining personal identifiable information or protected health information about a living person for research purposes.

3. Re-approval of Non-Exempt Human Studies – documentation that the Principal Investigator has current CITI training, plus annual continuing education (CE) human subjects protection training, for re-approval of non-exempt human research studies. All engaged Associate Investigators, Research Coordinators/Assistants and IRB-assigned Research Monitors must also have current CITI training and annual continuing education human subjects protection training by the time the study is reviewed for continuance, otherwise, these individuals will not be approved to continue on the study. The annual CE requirement can be fulfilled by taking the CITI Refresher Course.

4. New Exempt Studies – all new Exempt studies must document CITI training for the Principal Investigator only. Completion of this training must be received prior to study approval. Associate Investigators, Research Coordinators and Research Assistants are not required to have CITI training. There is no CE requirement for investigators conducting exempt research.

5. Change of Principal Investigator – all requests for a change in the investigators for Non-Exempt Human and Exempt studies must provide documentation that the new investigator has completed an approved CITI training course prior to approval.

6. FDA Regulated Studies – all new FDA regulated non-exempt human research studies that have an Investigational New Drug (IND) or an Investigational Device Exemption (IDE) must document completion of Good Clinical Practice (GCP) training for the Principal Investigator only. GCP training can be found on the CITI training website.

Completion of the PI GCP training must be received prior to study approval. It is optional that Associate Investigators and Research Coordinators also complete GCP training. Pass rate is 80%.

7. For questions concerning CITI and/or GCP training certification, please contact the 59 MDW IRB Office of Research Protocol Support at 59crd.protocol@us.af.mil.

My study has been approved through the IRB. When can I expect to receive my research funding from the IRB?
The IRB does not provide research funds and is not a sponsor of protocols. Many sponsors require an IRB-approved protocol before they send funds. You should check with 59 MDW/ST or the CIP program if you are a GHSE student regarding funding. Every funding agency has its own specifications for obtaining funding. The 59 MDW/ST weekly bulletin announcements regularly provide information on opportunities for research funding. The POC for receiving the bulletin is Ms. Alice Houy (210-292-8029; alice.houy@us.af.mil).

The 59 MDW Clinical Research Division (59 MDW/ST CRD), a subdivision of the 59 MDW/ST, supports Major Command-funded research, research involving human subjects, Graduate Medical Health Sciences Education scholarly activity, training of personnel involved in human subjects research, and the 59 MDW IRB through its Clinical Investigation Program (CIP), which is funded by Defense Health Program (DHP) operation and maintenance appropriated funds. The CIP is an essential component of medical care and teaching. The CRD CIP supports clinical investigation research for 59 MDW and SAMMC, SAMHS-assigned AF healthcare providers for the advancement and application of medical science for military and DoD beneficiary patient care. The CIP also supports operational health readiness training for GHSE students and other allied health programs. CIP DHP funds are intended to support USAF researchers with their IRB-approved GHSE and Clinical Investigations. Researchers requesting CIP funds must provide a copy of their IRB approval letter with their request for support. CIP funds cannot support any non-human/non-research or exempt activities or programs, other than non-exempt human subject research studies approved through IRB-designated reviewer determinations or the convened IRB (as required), regardless of any other federal policies that may be in effect. Based on the availability of CIP DHP funds, investigators can request funding for research publications that have been accepted by the publisher. The POCs for applying for and receiving CIP funding is Dr. Anneke Bush (210-292-7295; anneke.bush@us.af.mil) or Mr. Paul Barnicott (210-292-5687; paul.barnicott.1@us.af.mil).

Do I need to take my Case Study to the IRB?
You should take any project or study involving human participants to the IRB in order to receive an official determination on whether your study constitutes research or not. This is especially important if you are required or want to publish or present your work. The 59 MDW clearance process requires an IRB determination in order to complete a 59 MDW Form 3039, in accordance with 59MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*. The POC for questions regarding the Form 3039 publications clearance process is Dr. Rocky Calcote (210-292-5203; rocky.calcote.1@us.af.mil). You may obtain the 59 MDW Form 3039 HERE. Completed Form 3039 packages should be submitted to: 59CRDPubsPres@us.af.mil.

The IRB approved my protocol. How do they provide me research time?
When your commander or department head approves your protocol, you will be authorized to set-aside time to conduct research. The IRB does not authorize investigators to set-aside research time and should not be consulted if you have not obtained permission from your commander or department head to conduct research. If you are a staff member at the 59 MDW, your HRPP representative for medical care is Col Joseph Richards (210-292-7361; joseph.richards@us.af.mil). Your HRPP representative for graduate health programs is Col Tonya Rans (210-292-2117; tonya.rans@us.af.mil). Work with them to get time set-aside for conducting research. The 59 MDW role is to support the Air Force and DHA mission of conducting Defense Health Program-funded research and CIP-funded clinical research.

The IRB forms and templates are not letting me check boxes or easily insert language into fillable form fields. I am using an Apple Macintosh-based computer or device ... what is the problem?

Unfortunately, Apple Mac-based computers do not communicate or integrate well with the PC-based Microsoft Office documents that the IRB uses. Compatibility issues have historically been one of the major headaches when using Apple-based computers for word processing and office workflow. Even Microsoft Office for Mac users still runs into problems integrating documents created on a PC.

The simplest solution is to use a PC-based or government (CAC-enabled) computer when completing IRB forms.